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09/887,204	06/22/2001	Moshe Fleshner-Barak	1662/53002	7559

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EXAMINER	
FUBARA, BLESSING M	
ART UNIT	PAPER NUMBER
1618	
MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/887,204	FLESHNER-BARAK ET AL.	
	Examiner	Art Unit	
	BLESSING M. FUBARA	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 December 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *90-96 and 113-125* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *90-96 and 113-125* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Examiner acknowledges receipt request for extension of time, amendment and remarks filed 9/26/06. Claims 90, 91, 93 and 94 are amended. New claims 115-125 are added. Claims 90-96 and 113-125 are pending.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 90-96, 113, 114 and new claims 115-125 remain/are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement for reasons on record. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is New Matter rejection.

Claims 90 and 92 recite that methylphenidate from the first particles are into the stomach. The specification as filed does not contain a section where the methylphenidate is released from the first and second particles into the stomach. 35 U.S.C. 132(a) provides that "[n]o amendment shall introduce new matter into the disclosure of the invention."

The above rejection may be overcome by removing the new matter.

Response to Arguments

4. Applicant's arguments filed 12/07/07 have been fully considered but they are not persuasive.

5. Applicant argues:

6. a) *that the specification at page 23, lines 3-12 and page 19, line 31 to page 20, line 12 provide support for particles, first and second, releasing methylphenidate into the stomach.* However looking through the lines of the passages applicant refers to, the examiner does not find support for particles delivering methylphenidate to the stomach, support, the sections provided by applicant is reproduced below:

page 23, lines 3-12 as provided by applicant in the remarks

> An especially preferred capsule dosage form for pulsed delivery of methylphenidate contains two tablets (reservoirs) containing the drug and coated for timed delay of release. These two tablets are placed in contact with a coated GRDS [gastric retention delivery system] tablet that has…an immediate release dose of methylphenidate as its coating. **When the capsule enters the stomach, the gelatin capsule dissolves,…the immediate dose of methylphenidate is released and the GRDS tablet swells for gastric retention. The three tablet ensemble is retained in the stomach for an extended period. At the predetermined time, e.g. 4 hours, the second dose is released**…

Page 19, line 31 to page 20, line 12 as provided by applicant in the remarks

> **The expanding composition of this invention will retain these forms in the stomach until the delay time has passed whereupon the drug will be released in a burst or pulse fashion…Delayed dosage forms that are not coupled to gastric retention will deliver each such dose in a different part of the GI tract** with different absorption profiles for each of the doses. Such therapy would not be equivalent to taking three doses of the drug at the prescribed times, wherein the drug would have been absorbed from the stomach in each case.

7. Claims 110-121 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

8. Claims 119-121 recite the limitation "hydrophobic and hydrophilic" in lines 2 (claim 119) and line 1 of claim 120 and 121. There is insufficient antecedent basis for this limitation in the claim. Claim 93 does not recite hydrophobic and hydrophilic polymers.

9. For new claim 118, it is unclear what the difference is between water soluble resins, water insoluble resins, waxes, lipids and enteric resins on one hand and polymeric coating substance.

10. For new claim 118, the boundaries of the "substance' in polymeric coating substance is not defined.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

12. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

13. Claims 90-96, 113, 114 and new claims 115-125 remain/are rejected under 35 U.S.C. 103(a) as being unpatentable over Burnside et al. (US 6,322,819) in view of Swanson et al. (US 4,326,525) according to the rejections on record and reiterated herein.

Burnside discloses multiple pulsed dose drug delivery system (abstract) comprising a core (column 6, lines 52-56) that includes one or more amphetamine salts coated with immediate release coating and one or more amphetamine salts that are covered with enteric coating (column 3, lines 25-48; column 4), and additives, the additives are binders, disintegration agent, filling agent, surfactant, solubilizers and stabilizers (column 6, line 64; column 7, lines 1, 6, 11, 14 and 18). Hydroxypropyl methylcellulose is an example of a binder additive (column 6, lines 63-67); cross-linked carboxymethylcellulose (AC-DISOL), sodium starch glycolate (EXPLOTAB), crosslinked polyvinylpyrrolidone (PLASDONE XL) are examples of disintegration agents (column 7, lines 1-5); mannitol, lactose, polyethylene glycol are few of the fillers in Burnside (column 7, lines 6-10); PLURONIC is a surfactant in Burnside (column 7, lines 10-13); methylphenidate is specifically disclosed as an amphetamine derivative (column 7, lines 48-55).

The cross-linked carboxymethylcellulose (AC-DISOL), sodium starch glycolate (EXPLOTAB), crosslinked polyvinylpyrrolidone (PLASDONE XL) meet the limitation of the claimed disintegration agents. Claims 113 and 114 recite the properties of the composition and the recited properties are inherent to the composition.

New claim 115 recites the characteristic of the particles and is met by the art.

New claims 116 and 117 administer the composition of claims 90 and 93 to a person in need thereof to treat hyperactivity and since Burnside administers the dosage form and acknowledges that that methylphenidate can treat attention deficit hyperactivity (column 7, lines

51-55), the administered dosage would inherently treat hyperactivity and new claims 116 and 117 are met.

The prior art teaches the presence hydroxypropyl methylcellulose, cross-linked carboxymethylcellulose and sodium starch glycolate so that new claims 122-125 are met.

The particles of Burnside are coated with hydrophilic or hydrophobic polymers namely hydroxypropyl methylcellulose polyvinylpyrrolidone, ethylcellulose, EUDRAGIT polymers and other enteric polymers (column 7, line 42 to column 8, line 45) meeting new claims 118-121.

Burnside discloses a composition comprising disintegration agent and methylphenidate and the composition is multi-particulate with some cores coated with enteric coating material and others coated with immediate release coating materials. The formulation of Burnside does not contain tannic acid or tannin or gallototannic acid.

However, Swanson discloses a dosage form containing methylphenidate (column 7, line 16), tannic acid (column 7, line 44; column 8, line 16). Thus, Swanson is relied upon for disclosing methylphenidate formulation that comprises tannic acid. The claims recite ranges in amounts of superdisintegrants, hydrogel and tannic acid. However, there is no demonstration that the recited amounts provides unexpected results to the claimed dosage form. Specifically, Burnside is silent in the amounts of these ingredients, which implies that any amount in any combination would provide formulation for the effective release of methylphenidate. Furthermore, the claimed broad ranges suggests varied combinations in varied amounts. In the absence of factual evidence, the recited amounts of the hydrogel composition, the tannic acid and the superdisintegrants would not distinguish the claimed invention over the prior art.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare the methylphenidate multi-core dosage form according to Burnside. One having ordinary skill in the art would have been motivated to include tannic acid in the formulation of Burnside with the expectation of producing and providing multiple pulsed dose of amphetamine salts and specifically methylphenidate.

Response to Arguments

14. Applicant's arguments filed 12/07/07 have been fully considered but they are not persuasive.

Applicant argues:

b) *that the '819 patent to Burnside differs from the instant claims by not describing gastric retention vehicle that expands to promote retention of the dosage form in the patient's stomach in order to accomplish a pulsed gastric release and that the '819 patent is concerned with immediate release in the stomach and enteric release in the small intestine, that the desired release area for the 819 patent is in the intestine and not the stomach, that when the dosage form is coated, the release is delayed.* In response to the foregoing argument it is noted that expansion of the retention vehicle is a property of the vehicle, and to promote retention derives from the expandable properties of the vehicle. Further applicant argues about different embodiments of the '819 patent but appears to support both delivery in the small intestine and the stomach and the claims require deliver into the stomach and does not exclude delivery into the intestine. Specifically the claims and the '819 patent use the same polymers for coating the particles. Applicant refers to column 8, lines 14-21 of the '819 patent as desiring release in the

after it passes through the acidic stomach, but this is but one embodiment of the '819 patent and applicant in the opening remarks of this section admits that the '819 patent release into the stomach. Applicant has also referred to column 4, lines 27-31 and column 10, line 6 to column 11, line 67 to support applicant's argument that the '819 patent releases into the small intestine, but as noted previously, applicant has admitted to the '819 patent releasing into the stomach and the claims have not excluded release into the small intestine. Applicant's arguments cannot negate the fact that the '819 patent discloses release into the stomach and teaches the same polymers in the matrix and the coat as the claims.

b) *that '819 patent does not disclose the use of tannic acid in the composition as the claimed composition does*. With respect to tannic acid, the examiner agrees with applicant that the '819 patent does not teach presence of tannic acid and Swanson provides the teaching of tannic acid with methylphenidate. In this regard, applicant is arguing against the references individually, and one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. Examiner recognizes that combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion can only establish obviousness, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. In the present case, it is the combination of Burnside ('819) and Swanson ('525) that renders obvious the claimed composition by Swanson providing the teaching of tannic acid.

c) *that Swanson, the '525 patent cannot remedy the deficiency of Burnside, the '819 patent*, but the '525 patent was used to provide tannic acid and no other deficiency needs remedy.

d) *that Swanson, the '525 patent is an osmotic delivery device*, but Swanson was relied upon for teaching that methylphenidate can be formulated with tannic acid.

e) *that in order to use Swanson, the '525 patent with the '819 patent, one may have had to modify the osmotic dosage form of Swanson*, but no such modification is necessary because the rejection is Burnside in view of Swanson and as stated above Swanson was relied upon for teaching that methylphenidate can be formulated with tannic acid.

f) *that Swanson, the '525 patent uses tannic acid to increase the solubility of the beneficial agent by its interaction with the beneficial agent*, but in this case applicant appears to have different use for tannic acid and the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985). Tannic acid is tannic acid in the claims and if the tannic acid performs certain use in the claimed composition, it would also perform the function in the composition of Burnside.

Therefore, claims 90-96 and 113-125 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burnside et al. (US 6,322,819) in view of Swanson et al. (US 4,326,525).

15. Claims 90, 93, 116, 117 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burnside et al. (US 6,322,819) in view of Swanson et al. (US 4,326,525) and further in view of (US 5,874,090).

Burnside in view of Swanson has been shown above to render obvious claims 90 and 93 obvious. While Burnside recognizes that methylphenidate is indicated in the treatment of attention deficit hyperactivity disorder (column 7, lines 51-55), Burnside does not specifically

describe treating attention deficit disorder. However, Baker teaches that methylphenidate can be administered to a subject in need thereof to treat hyperactivity (claims 1-10 and 16). Therefore, taking the teachings of Burnside, Swanson and Baker together, the person of ordinary skill in the art at the time the invention was made would have reasonable expectation of success that administering the composition of Burnside containing the tannic acid of Swanson to person in need thereof, would treat hyperactivity as suggested by Baker.

No claim is allowed.

16. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BLESSING M. FUBARA whose telephone number is (571)272-0594. The examiner can normally be reached on 7 a.m. to 5:30 p.m. (Monday to Thursday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

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